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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,868	03/16/2004	Qun-Sheng Ji	OS-10002	8803
38724 7590 12/28/2007 OSI PHARMACEUTICALS, INC. 41 PINELAWN ROAD MELVILLE, NY 11747			EXAMINER PAK, MICHAEL D	
			ART UNIT 1646	PAPER NUMBER
			MAIL DATE 12/28/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Office Action Summary</p>	Application No. 10/801,868	Applicant(s) JI, QUN-SHENG	
	Examiner Michael Pak	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,9,13,14,21,22,24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7,8,10-12,15-20,23 and 26-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Amendment filed October 1, 2007 has been entered.
2. Applicant's arguments filed October 1, 2007, have been fully considered but they are not found persuasive.
3. Claims 1, 5, and 7-24 are withdrawn. Claims 2-4, 6, and 25-28 are examined below.
4. This application contains claims 1, 5, 7-24 drawn to an invention nonelected with traverse in the reply filed on June 29, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-4, 7-8, 10-12, 15-20, 23, and 26-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims recite receptors by name only which is ambiguous because no structure is provided and the metes and bounds of the term is not clear. Claimed term "Ret receptor kinase" by name only without structure is ambiguous because the metes and bounds of the term is not clear. The term is not defined and the boundary of the term is not clear. Other receptor domains are also recited by name only without structure and the metes and bounds are not clear.

Applicants argue that the term is clear because the cited references refer to Ret receptor kinase as only one molecule encoded by one gene. However, it should be noted that most scientific articles do not discuss the metes and bounds of the generic term and are discussing the specific species in a particular reference. Furthermore, there are many different types of mutations of Ret kinase species in the literature. If the function is not provided with structure which is sufficient to narrow the claims then the metes and bounds are not clear. For example when is a Ret receptor kinase which can have unlimited substitution different from any other kinase receptor? For example the EGFR is a kinase receptor and appears to meet the limitations of the Ret receptor kinase as claimed without structural limitation. Thus, how is one skilled in the art to determine when Ret receptor kinase is different from other receptor kinases if it is not limited by structure. Furthermore, the names of receptors change over time or are named differently by different inventors or scientists thus it becomes a relative term. Furthermore, if the Ret kinase receptor can have unlimited changes then how is one skilled in the art able to determine what is the specific amino acid sequence number that should be substituted. Furthermore, if the Ret receptor kinase can have unlimited

mutations then when is Ret kinase receptor a rat receptor versus the human receptor or any other species.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 7-8, 10-12, 15-20, 23, 26-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Rizzo et al. (J. Biol. Chem., 1996).

Rizzo et al. disclose a hybrid receptor which is EGFR/RET chimera (page 29498-29499). The claim limitations do not exclude the receptors of Rizzo et al. because the claims recite receptors by name only.

Applicants argue that Rizzo et al. uses the EGFR receptor thus it is not a Ret receptor kinase in the extracellular domain. However, the claims encompass an unlimited changes to the Ret receptor kinase claimed and thus the product by process limitation is met by the chimera of Rizzo et al. Furthermore, Rizzo et al. disclose on page 29501 that the EGFR/Ret-thr-918 does not require a ligand for activation. The cytoplasmic domain is heterologous to the extracellular domain. The limitations to genomic encoding is a product by process claim which does not further limit the unlimited structural modification claimed. The limitations to human is a product by

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process limitation also and does not further limit the unlimited structural modification claimed.

7. No claim allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached on 8:00 - 2:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Pak
Primary Patent Examiner
Art Unit 1646
11 December 2007